

House Rules for Participants in Clinical Study Programs at Linear Clinical Research

Thank you for agreeing to participate in a research study at Linear.

It is a mandatory requirement to agree to the following house rules prior to admittance to the clinical unit.

These house rules may at first seem onerous, however, they are in place to protect your safety and the safety of those around you, including other participants and staff. Your conduct within a research study has an impact on the overall results of the study – if you do not follow instructions of staff the whole study may become invalid. This could have the effect of other people not having the benefit of participating and ultimately it may delay the availability of a new life-saving medicine to those who need it.

PLEASE NOTE THAT FAILURE TO COMPLY WITH THESE HOUSE RULES MAY RESULT IN DISMISSAL FROM THE STUDY, WHICH WILL DIRECTLY AFFECT YOUR REMUNERATION AND PREVENT PARTICIPATION IN OTHER LINEAR STUDIES.

Linear Background

Linear Clinical Research is a not-for-profit organisation that conducts clinical research on behalf of sponsor companies to advance medical research.

Linear is a fully owned subsidiary of the Harry Perkins Institute of Medical Research.

Prior to commencing any study, it is approved by an independent Human Research Ethics Committee (HREC).

1. General

- a) Please note that your participation in the study always remains voluntary.
- b) During your stay, Linear accepts no responsibility for your personal belongings (including your vehicle).
- c) Participants are advised not to interfere with or touch any of the clinical or computer equipment within the Linear facility. You will be held financially responsible for any wilful damage to Linear property that you cause during your stay.

2. Admission/Check-In

- a) Always be punctual for your scheduled visits to the facility. Being more than 30 minutes late for any appointment could affect your ongoing participation in the study and/or remuneration. Many procedures are time-critical, and scheduled appointments must therefore be kept. **Please call ahead if you are going to be late.**
- b) For the security of all volunteers and staff during in-house periods, your belongings will be searched at check-in, check-out, and at any other time that may be deemed necessary.
- c) Please bring all of your required belongings, including toiletries, with you on the day of check-in as it is unlikely that you will be allowed to leave the clinical unit during your scheduled stay. You will be confined to (must remain within) the clinical unit for the duration of the study.
- d) You will be given a locker for your personal use. Please ensure that you return the locker key prior to check out. **If the key is not returned, a replacement fee of \$50 will be deducted from your final remuneration.**

3. Study Procedures

- a) During the study a number of samples will be collected (e.g. blood, urine). The types and number of samples required will vary according to the study protocol and are outlined in the Participant Informed Consent Form you signed at your screening visit.
- b) You must NOT provide urine samples for other participants. If you are participating in a urine-collection study, you must take only your urine container with you to the bathroom and fill it with your urine.
- c) For your personal safety, you will be asked to stay on your bed for a period of time after every dose of study medication as defined in the approved study protocol. This will be advised to you by a member of the clinic team.
- d) Linear staff will perform a “hand and mouth check”, where required, to ensure that you have swallowed any oral medication completely.

4. Facilities and Common Areas

- a) Other than the clinical unit area, recreational/dining room, quiet lounge, and the restrooms/showers, all other rooms are restricted to Linear staff.
- b) Health and safety standards require that the clinical unit be kept clean and uncluttered.
- c) Participants are responsible for tidying their bedside table, making their bed when not in use and keeping the area around the bed free from all objects to allow staff to work safely in the area.
- d) Do not use any bed other than the one that has been assigned to you.
- e) Meals and drinks are not to be consumed in the ward area unless study staff have permitted it. Unless required by the protocol, all meals will be provided in the dining room.
- f) You are not allowed to enter the Linear kitchen for any reason.
- g) No bags or luggage will be permitted at the bedside or in the clinical ward area. They must be stored in the locker assigned to you in the unit corridor.
- h) You should only bring essential items in with you, e.g., clothing, toiletries, personal entertainment (MP3 player, laptop), as only one large locker & one small bedside locker will be assigned to you.
- i) Free Wi-Fi is available for all participants for the duration of your visit using our “Patient Wi-Fi network” The password can be obtained from Linear staff at any time.

PLEASE NOTE: Under no circumstances can participants connect their personal computers / laptops, etc. to the “Linear staff network”. You must not plug anything into any network ports within the Linear facility.

5. Clothing

- a) Please bring comfortable, non-restrictive, appropriate day and night clothing with you that is suitable for study procedures (e.g., blood sampling, vital signs, ECG measurements). Unless stated in the protocol your own clothes will be worn at all times.
- b) Both male and female participants & staff will be in the clinic. Therefore, we ask that you dress appropriately and are suitably covered at all times.
- c) Proper footwear (shoes, slippers, flip-flops) must be worn when you are not in your bed. Walking around barefoot or in socks only is not allowed. Socks alone are not sufficient protection for your feet.
- d) There are no laundry facilities available. Therefore, ensure you have an adequate supply of clean clothing for the duration of your stay.

6. *Personal Hygiene*

- a) During in-house periods it is expected that you shower, shampoo your hair and brush your teeth at least once a day.
- b) You must provide your own toiletries (unless study procedures dictate otherwise). Towels will be provided and it is expected that you will use one towel for a 2-day period.
- c) You are obliged to keep the restrooms and showers clean. Please advise staff if any stock (e.g., towels, paper towels) needs replenishing.

7. *Expected Standards of Behaviour*

- a) Please show respect for others in both your behaviour towards, and conversations with, staff and other participants.
- b) Pornographic material of any type is prohibited.
- c) Intimacy with other participants, your visitors, or staff members is strictly prohibited.
- d) Swearing, sexual comments, harassment, obscene gestures, or any other inappropriate behaviour will not be tolerated.
- e) Provoking, encouraging or engaging in fighting or horseplay will not be tolerated.
- f) Making physical, verbal or written threats or defamatory comments about Linear or any of its staff may constitute cause for immediate dismissal with no further payment.
- g) Causing distress to other participants or staff or jeopardising the study's data may result in you being removed from the trial with no payment.
- h) Participants are advised not to interfere with or touch any of the clinical equipment in the clinical unit or at your bedside. You will be accountable for reimbursement, repair or replacement for wilful destruction of property.
- i) The information and data that we collect from you is confidential; therefore, you are not permitted to view other participant's files or to discuss the study or your results with other participants.
- j) If you are found to have been untruthful or misleading regarding your participation in the study (e.g., with information given to the study staff in relation to being accepted onto the study), you may be withdrawn with no, or only a partial payment.

8. *Visitors*

- a) Visiting hours will vary according to the procedures required by the protocol and will be determined by the clinic staff. As a general rule, visitors will be permitted on weekends only, from **14:00 - 16:00 hrs (Saturday and Sunday)**, but this will be at the discretion of the clinic staff and you will be informed if visiting is not permitted.
- b) Please note that study procedures always take precedence over visiting hours.
- c) As certain studies may preclude visitors altogether, Linear has the right to shorten and/or cancel visiting hours as required.
- d) Due to the nature of the activities performed in the clinic, children are not permitted to visit the facility.
- e) All visitors must report to reception or clinic staff first and be signed in/out.
- f) Visitors will be provided with a visitor tag that must be displayed at all times.
- g) Visitors will be subjected to bag / pocket searches prior to entry to the unit.

- h) Visitors are not allowed under any circumstances to be in the clinical unit area. All visitors will be seen in the participant recreational areas, unless advised otherwise by the clinic staff.
- i) Visitors must not bring in food or drink items, even for their own personal consumption. These will be confiscated and returned upon leaving.
- j) You are responsible for the behaviour of your visitors while they visit you.
- k) Your visitors may be asked to leave if you or they are non-compliant with these rules.
- l) Visitation rights may be taken away should you or your visitors fail to adhere to these rules.

9. Food and Beverages

- a) As food and beverages may interfere with study results, only food provided by the study staff is to be consumed during your stay. You will not be served the following during your confinement, unless allowed or required by the protocol: grapefruit/grapefruit juice, oranges/orange juice, cordial, hot or cold caffeinated beverages and chocolate. There may be additional restrictions to your diet (specific to your study), which will be outlined in your consent form.
- b) You will be served meals and snacks according to the study schedule.
- c) Food provided must be consumed during your allocated meal schedule, and all leftover food will be disposed of. You must NOT save food for consuming at a later time.
- d) If required by the protocol you will have to eat the exact amount of food that has been prepared for you.
- e) Food must not be shared with others.
- f) Hot drinks will only be served during mealtimes. Water can be consumed all day when not restricted by the protocol.
- g) Unless staff have permitted, or it is a requirement of the protocol, all meals will be consumed in the dining room.
- h) If you need anything from the kitchen, do not enter the kitchen – please ask a member of staff for assistance.
- i) It is important that you inform the staff at either your screening visit or prior to check-in, about any special dietary needs (vegetarian, food allergy, etc.), as we will not be able to change menus once you check in.
- j) Protocol-defined dietary restrictions (if applicable) must be followed when you check out of the facility as per instructions and advice outlined in your participant informed consent form and/or by study staff.

10. General Rules

- a) Smoking is strictly prohibited.
- b) The taking of photos or the recording of video (including on mobile phones) within Linear is not permitted. A fine will be imposed on any participant found taking photos or recording activities.
- c) During confinement periods you must not leave or attempt to leave the clinical unit (beyond the double swing doors) without staff supervision or approval.
- d) Mobile phones may be used providing they do not interfere with the conduct of the study.
- e) If using a device to listen to music or watch movies/TV you must bring in your own earphones and use them so as not to disturb the other participants.

- f) Strenuous exercise may cause abnormal laboratory results and is therefore not allowed during your participation on the study, unless required by the protocol.
- g) Alcohol, illegal drugs, vitamins, prescription, or over-the-counter medications are not allowed to be brought into the clinical unit during your stay. You can only bring in medications approved by the Research Physician at your screening visit. You can continue to take these medications as prescribed, but the clinic team will store them in a locked cupboard and provide them to you at prescribed times.
- h) You will be required to be in your bed at 23:00 hrs each night. Televisions and lights for reading will be permitted until midnight, but a quiet environment must be maintained.
- i) During your stay in the unit, you may become privy to information related to the actual study, other trial participants, and the staff. This information must always be treated with full confidentiality.
- j) You may not, under any circumstances, access or read other participant’s notes or results.
- k) If you would like to review or access your own notes or results this must be formally requested through a Linear staff member so your records can be reviewed with you by a Research Physician to ensure that these are understood by you.

11. House Rules Non-Compliance

- a) Failure to comply with any of the house rules and expected standards of behaviour may result in a fine. This will be a minimum of \$100 per transgression (at the discretion of Linear Management). Any fines will be deducted from your final remuneration.
- b) Transgressions may result in immediate dismissal from the study with no payment and a ban from further studies at Linear.

12. Complaints

- a) If you wish to make a complaint about any aspect of your stay at Linear, please speak with a member of staff who will assist you in making sure the issue is raised and responded to by Management. Please be assured all complaints are taken seriously and you will be informed within five business days of the outcome of any actions taken in relation to your complaint.

We hope you enjoy your stay at the Unit. Should you have any queries, please feel free to ask the study staff at any time, day or night (24/7).

Thank you for your cooperation and support of medical research.

Kind regards,

Linear Management

House Rules for Participants Agreement		
I have read and understood the rules detailed within this document and have had the chance to discuss any queries I had with the study staff.		
By signing below, I agree to abide by Linear’s House Rules and understand that Linear Staff reserve the right to enforce these rules at any time during my stay.		
_____	_____ / /
Participant Name	Signature	Date (DD/MMM/YYYY)